D. Remarks

Claims 1-18 are pending and under examination in the subject application. Applicant has not amended, canceled or added any claims hereinabove.

Information Disclosure Statement

In the Office Action the Examiner stated that unless references cited in the specification are submitted on a separate paper, such as PTO-1449, they will not be considered.

In response, applicant is attempting to obtain copies of such references and may submit copies at a later time.

Sequence Compliance

In the Office Action the Examiner stated that the applicant contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in Rule 821.

In response, applicant without conceding the correctness of the Examiner's position but to expedite prosecution of the subject application encloses a computer diskette containing the sequence listing in computer readable form. Applicant attaches hereto, as **Exhibit A,** a paper copy of the computer readable form of the sequence listing. Applicant attaches hereto as **Exhibit B** a Statement in Compliance with 37 C.F.R. §1.821(f) certifying that

the computer readable form contains the same information as the paper copy of the sequence listing attached as **Exhibit A**.

In addition, applicant has hereinabove amended the specification to include references to the sequence identifier information (i.e., SEQ ID NO:) as required by 37 C.F.R. §1.821(d). This amendment does not involve any issue of new matter. Therefore, entry of this amendment is respectfully requested.

Claims Rejected Under 35 U.S.C. §101

In the February 1, 2006 Office Action, the Examiner stated that claims 1-18 are rejected under 35 U.S.C. §101 as allegedly not supported by either a specific and substantial asserted utility or a well established utility. Moreover, the Examiner alleged that applicant's asserted use, while found to be specific, was not found to be both a specific and substantial utility.

The Examiner also indicated that applicant discloses, inter alia, an application of the assembly as a "drug discovery" tool. However, applicant notes that the specification refers to drug delivery, not discovery.

The Examiner also indicated that, regarding applicant's asserted utility, and the consideration of therapeutic or pharmacological utilities, MPEP §2107.03 requires that, inter alia, evidence of pharmacological or biological activity is relevant to the asserted therapeutic use.

In response, applicant notes that the asserted use regards the delivery of the biologically active material, not the biologically

active material itself, and, as such MPEP §2107.03 is not germane to assessing the asserted utility.

The Examiner also stated that the cited uses of the claimed assembly rely upon speculated utilities or generic applications that are not drawn from any well known application of the properties of the instantly claimed invention. The Examiner further stated that his review of the pertinent art related to surface attached nucleic acids has not revealed any case of modifying a surface bound nucleic acid sequence by means of a separate catalytic nucleic acid enzyme. The Examiner also indicated that, as such, applicant's claimed invention, drawn to an assembly comprising catalytic leg units that modify tethered nucleic acid fuel substrates, lacks any substantial utility. The Examiner further noted that the instant claims are not limited to embodiments wherein the cleaved portion of the oligonucleotide substrate is a drug, nor do the claims recite any limitation wherein the solution that cleaved oligonucleotide portions are released into contains any targets for drug delivery.

In response, applicants note that the claimed invention (of claim 1) is the macromolecular assembly, and not the method of drug delivery or the oligonucleotide tethered to a surface. As such, only the utility of the claimed assembly, i.e. the claimed invention, is required. In addition, applicant notes that in assessing utility, MPEP §2107 (II)(B)(3)(ii) indicates that the Examiner should "ensure that there is an adequate nexus between the evidence [of utility] and the properties of the now claimed subject matter as disclosed in the application as filed." Applicant maintains that because applicant has demonstrated actual oligonucleotide cleavage by the macromolecular assembly and release

of oligonucleotide, the nexus between the properties of the claimed invention and the utility *has* been shown, and that there is no requirement to list uses of the claimed assembly to comply with the utility requirement. In support of this applicant notes that oligonucleotide drugs are commercially available. Applicant attaches hereto as Exhibits 1 and 2 evidence of two oligonucleotide drugs, Vitravene and Macugen respectively.

Applicant further notes that, according to MPEP §2107 and to the Revised Interim Utility Guidelines Training Manual, (the "Utility Guidelines"), an invention is considered to meet the utility requirement if it has (1) a credible utility and (2) either (a) a specific and substantial utility or (b) a well-established utility.

Credible Utility

The test for credible utility is that an assertion of utility is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion (see Utility Guidelines).

Applicant notes that an asserted use for the claimed invention is stated in the specification at page 10, lines 10-12, specifically, for drug delivery, and that the Examiner has not challenged applicant's position that the invention has a credible utility. Accordingly, applicant maintains that the claimed invention has a credible utility.

Applicant notes that only one *use* need be shown for the utility requirement to be met (see MPEP §2107 (II)(B)(1)(ii)).

In addition, according to the Utility Guidelines and MPEP §2107.01 (I) a substantial utility is established if applicant defines "a real world use". Applicant maintains that drug delivery is a real world use, and that such oligonucleotides drugs are actual, and not merely theoretical.

Accordingly, applicant maintains that the asserted utility is both (1) a credible utility and (2) a specific and substantial utility, Applicant therefore respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

Well Established Utility

Applicant also maintains that the claimed invention has a well established utility. The Utility Guidelines state that a well established utility is a "utility which is well known, *immediately apparent, or implied* by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one of skill in the art" (emphasis added).

Applicant notes that the usefulness of cleaving bound oligonucleotides, and thus the simultaneous release of a portion of the oligonucleotide, is immediately apparent to one of skill in the art. In addition, a well established utility is implied by the specification's disclosure of the use of the claimed invention for drug delivery. Accordingly, applicant maintains (although not necessary to satisfy the Guidelines) that the claimed invention has a well established utility.

Accordingly, applicant maintains that the claimed invention fulfills the utility requirement, and respectfully requests the Examiner reconsider and withdraw this ground of rejection.

Claims Rejected Under 35 U.S.C. §112

The Examiner rejected pending claims 1-18 under 35 U.S.C. §112, first paragraph, on the ground that because the claimed invention is allegedly not supported by either a specific and substantial asserted utility, or a well established utility, one skilled in the art would not know how to use the claimed invention.

In response, applicant respectfully traverses the rejection. In particular, applicant notes that the arguments presented hereinabove establish that the claimed invention meets the utility requirement under 35 U.S.C. §101 and specifically show that the claimed invention has a specific and substantial utility. Furthermore, the specification describes the process of catalytic nucleic leg units of the macromolecular assembly binding to an oligonucleotide tethered to a surface and cleaving the oligonucleotide releasing "product" (i.e. a portion of the oligonucleotide) into solution (specification at page 6, lines 3-6). Accordingly, applicant maintains that one skilled in the art would readily know how to use the claimed invention. Applicant therefore respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

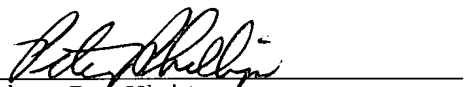
Double Patenting

The Examiner has made a provisional obviousness-type double patenting rejection of claims 1-18 over claims 1-18, 20-21 of co-pending application No. 10/189,103. Because the rejection is provisional, applicant will defer consideration of whether the obviousness-type double patenting rejection is proper.

If a telephone interview would be of assistance in advancing prosecution of the subject application, the undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

No fee is deemed necessary in connection with the filing of this Communication. If any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account Number 03-3125.

Respectfully submitted,



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